

(70180)

<b>Medical Benefit</b>		<b>Effective Date:</b> 10/01/14	<b>Next Review Date:</b> 11/18
<b>Preauthorization</b>	No	<b>Review Dates:</b> 07/12, 07/13, 07/14, 07/15, 11/15, 11/16, 11/17	

**Preauthorization is not required.**

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>With indication for hip replacement who would outlive a traditional prosthesis and have no contraindication for hip resurfacing</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Metal-on-metal total hip resurfacing device</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Any traditional total hip arthroplasty device</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Symptoms</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With indication for hip replacement who would outlive a traditional prosthesis and have no contraindication for hip resurfacing</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Partial hip resurfacing device</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Any traditional total hip arthroplasty device</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Symptoms</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related morbidity</li> </ul>

### Description

Hip resurfacing is an alternative to total hip arthroplasty (THA; also known as hip replacement) for patients with advanced arthritis of the hip. Total hip resurfacing (THR) describes the placement of a shell that covers the femoral head together with implantation of an acetabular cup in patients with painful hip joints. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head. Available prostheses are metal-on-metal devices.

### Summary of Evidence

For individuals who have an indication for hip replacement who would outlive a traditional prosthesis and have no contraindication for hip resurfacing who receive a metal-on-metal total hip resurfacing device or a partial hip resurfacing device, the evidence includes two randomized controlled trials, numerous large observational studies, large registry studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, health status measures, quality of life, and treatment related morbidity. The efficacy of THR performed with current techniques is similar to that for THA over the short-to-medium term, and

THR may permit easier conversion to a THA for younger patients expected to outlive their prosthesis. Based on potential ease of revision of THR compared with THA, current evidence supports conclusions that hip resurfacing (partial or total) presents a reasonable alternative for active patients who are considered too young for THA—when performed by surgeons experienced in the technique. The literature on adverse effects (e.g., metallosis, pseudotumor formation, implant failure) is evolving as longer follow-up becomes available. Due to the uncertain risk with metal-on-metal implants, the risk-benefit ratio needs to be considered carefully on an individual basis. In addition, emerging evidence has suggested an increased risk of failure in women, possibly due to smaller implant size. Therefore, these factors should also be considered in the overall patient evaluation for THR, and patients should make an informed choice with their treating physicians. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

### Policy

Metal-on-metal total hip resurfacing with a device system approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** as an alternative to total hip replacement when the patient:

- Is a candidate for total hip replacement; AND
- Is likely to outlive a traditional prosthesis; AND
- Does not have a contraindication for total hip resurfacing (See Policy Guidelines).

Partial hip resurfacing with an FDA-approved device may be considered **medically necessary** in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal implants and meet the following criteria:

- The patient is a candidate for total hip replacement; AND
- Is likely to outlive a traditional prosthesis; AND
- The patient has known or suspected metal sensitivity or concern about potential effects of metal ions; AND
- There is no more than 50% involvement of the femoral head; AND
- There is minimal change in acetabular cartilage or articular cartilage space identified on radiography.

All other types and applications of hip resurfacing are considered **investigational**.

### Policy Guidelines

The U.S. Food and Drug Administration (FDA) lists several contraindications for total hip resurfacing. These contraindications include, but are not limited to, the following:

- Bone stock inadequate to support the device due to:
  - severe osteopenia or a family history of severe osteoporosis or severe osteopenia
  - osteonecrosis or avascular necrosis with more than 50% involvement of the femoral head
  - multiple cysts of the femoral head (more than one cm)
- Skeletal immaturity
- Vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Known moderate to severe renal insufficiency

- Severely overweight
- Known or suspected metal sensitivity
- Immunosuppressed or receiving high doses of corticosteroids
- Females of child bearing age due to unknown effects on the fetus of metal ion release.

A 2012 FDA advisory panel of experts identified young males with larger femoral heads as the best candidates for hip resurfacing systems. The FDA advises that a metal-on-metal hip implant should be selected only after determining that the benefit-risk profile of using a metal-on-metal hip implant outweighs that of using an alternative hip system. Factors to consider include the patient's age, sex, weight, diagnosis, and activity level. Patients should be informed about the benefits and risks of metal-on-metal hip implants, including the risk that the hip implant may need to be replaced. Patient expectations and the potential complications of surgery with a metal-on-metal hip implant should be discussed.

### Background

THR has been investigated in patients with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis as an alternative to THA, particularly in young active patients who would potentially outlive a total hip prosthesis. Therefore, hip resurfacing could be viewed as a time-buying procedure to delay the need for a THA. Proposed advantages of THR compared with THA include preservation of the femoral neck and femoral canal, thus facilitating revision or conversion to a THR, if required. In addition, the resurfaced head is more similar in size to the normal femoral head, thus increasing the stability and decreasing the risk of dislocation compared with THA.

THR has undergone various evolutions, with modifications in prosthetic design and composition and implantation techniques. For example, similar to total hip prostheses, the acetabular components of THR have been composed of polyethylene. However, over time it became apparent that device failure was frequently related to the inflammatory osteolytic reaction to polyethylene debris wear particles. Metal acetabular components have since been designed to improve implant longevity. Sensitivity to wear particles from metal-on-metal (MoM) chromium and cobalt implant components are of increasing concern.

In January 2013, the FDA issued a safety communication on MoM hip implants (both THA and THR). This information was based on the FDA's current assessment of MoM hip implants, including the benefits and risks, the evaluation of the published literature, and the results of the June 2012 Orthopaedic and Rehabilitation Devices Advisory Panel meeting. As of January 2013, the FDA stated that it had insufficient scientific data to specify a concentration of metal ions in a patient's body or blood that would produce adverse systemic effects. In addition, the reaction seems to be specific to individual patients, with different patients having different reactions to the metal wear particles.

### Regulatory Status

In May 2006, the FDA approved the Birmingham Hip Resurfacing (BHR; Smith & Nephew Orthopaedics, Cordova, TN) system, a MoM resurfacing system, through the premarket approval (PMA) process for use in patients requiring primary hip resurfacing arthroplasty for noninflammatory or inflammatory arthritis. This decision was primarily based on a series of 2385 patients who received this device by a single surgeon in England. A number of postapproval requirements were agreed to, including the following items:

- Study longer term safety and effectiveness through 10-year follow-up of the initial 350 patients in the patient cohort that was part of the PMA.

- Study the “learning curve” and the longer term safety and effectiveness of the BHR in the United States by studying 350 patients at up to eight sites where clinical and radiographic data will be assessed annually through five years and at 10 years. Also, determine cobalt and chromium serum concentration and renal function in these patients at one, four, and 10 years.
- Implement a training program to provide clinical updates to investigators.

Two additional MoM hip resurfacing systems have been approved: in 2007, the Cormet™ Hip Resurfacing System (Corin, Tampa, FL) and, in 2009, the Conserve® Plus Total Hip Resurfacing System (MicroPort Orthopedics, Arlington, TN). Both implants were approved for skeletally mature patients with either: noninflammatory degenerative arthritis (e.g., osteoarthritis and avascular necrosis); or inflammatory arthritis (e.g., rheumatoid arthritis). (Note: patients with the latter arthritis might be individuals who, due to younger age or increased activity level, may not be suitable for traditional THA because it would increase the possibility of requiring ipsilateral hip joint revision.)

Various devices have been cleared for marketing by FDA through the 510(k) process for partial hip (femoral) resurfacing. Some surgeons may be using a femoral resurfacing component together with an acetabular cup (total arthroplasty component) as an off-label application.

As noted above, in January 2013, FDA issued a safety communication on MoM hip implants (including both hip resurfacing and hip replacement). FDA stated that MoM hip implants have unique risks in addition to the general risks of all hip implants. Described below, are some of those risks:

- With MoM implants, some tiny metal particles wear off of the device around the implant, which may cause damage to bone and/or soft tissue surrounding the implant and joint.
- Some of the metal ions released will enter the bloodstream and travel to other parts of the body, where they may cause symptoms or illnesses elsewhere in the body (systemic reactions).

Currently, FDA does not have enough scientific data to specify the concentration of metal ions needed in a patient’s body or blood to produce adverse systemic effects. In addition, the reaction seems to be patient-specific.

PMA product code: NXT.

### Related Protocol

Surgical Treatment of Femoroacetabular Impingement

---

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Blue Cross and Blue Shield Association Technology Evaluation Center. Metal-on-metal total hip resurfacing. TEC Assessments. 2007; Vol 22, Tab 3.
2. Vendittoli PA, Lavigne M, Roy AG, et al. A prospective randomized clinical trial comparing metal-on-metal total hip arthroplasty and metal-on-metal total hip resurfacing in patients less than 65 years old. *Hip Int.* 2006; 16 Suppl 4:73-81. PMID 19219833
3. U.S. Food and Drug Administration Center for Devices and Radiological Health. Summary of safety and effectiveness data: Birmingham Hip Resurfacing (BHR) System. 2006; [http://www.accessdata.fda.gov/cdrh\\_docs/pdf4/p040033a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040033a.pdf). Accessed July 7, 2015.
4. Australian Orthopedic Association. National Joint Replacement Registry Annual Report. 2006.
5. American Academy of Orthopaedic Surgeons (AAOS). Modern metal-on-metal hip implants: A technology overview 2011; <http://www.aaos.org/news/aaosnow/jan12/cover1.asp>. Accessed July 7, 2015.
6. U.S. Food and Drug Administration. FDA Safety Communication: Metal-on-Metal Hip Implants. 2013; <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm335775.htm>. Accessed July 7, 2015.
7. Nunley RM, Della Valle CJ, Barrack RL. Is patient selection important for hip resurfacing? *Clin Orthop Relat Res.* Jan 2009; 467(1):56-65. PMID 18941859
8. Marker DR, Strimbu K, McGrath MS, et al. Resurfacing versus conventional total hip arthroplasty - review of comparative clinical and basic science studies. *Bull NYU Hosp Jt Dis.* 2009; 67(2):120-127. PMID 19583538
9. Jiang Y, Zhang K, Die J, et al. A systematic review of modern metal-on-metal total hip resurfacing vs. standard total hip arthroplasty in active young patients. *J Arthroplasty.* Apr 2011; 26(3):419-426. PMID 20851564
10. Quesada MJ, Marker DR, Mont MA. Metal-on-metal hip resurfacing: advantages and disadvantages. *J Arthroplasty.* Oct 2008; 23(7 Suppl):69-73. PMID 18922377
11. Haddad FS, Konan S, Tahmassebi J. A prospective comparative study of cementless total hip arthroplasty and hip resurfacing in patients under the age of 55 years: a ten-year follow-up. *Bone Joint J.* May 2015; 97-B(5):617-622. PMID 25922454
12. Mont MA, Seyler TM, Ragland PS, et al. Gait analysis of patients with resurfacing hip arthroplasty compared with hip osteoarthritis and standard total hip arthroplasty. *J Arthroplasty.* Jan 2007; 22(1):100-108. PMID 17197316
13. Lavigne M, Therrien M, Nantel J, et al. The John Charnley Award: The functional outcome of hip resurfacing and large-head THA is the same: a randomized, double-blind study. *Clin Orthop Relat Res.* Feb 2010; 468(2):326-336. PMID 19543863
14. Garbuz DS, Tanzer M, Greidanus NV, et al. The John Charnley Award: Metal-on-metal hip resurfacing versus large-diameter head metal-on-metal total hip arthroplasty: a randomized clinical trial. *Clin Orthop Relat Res.* Feb 2010; 468(2):318-325. PMID 19697090
15. Azam MQ, McMahan S, Hawdon G, et al. Survivorship and clinical outcome of Birmingham hip resurfacing: a minimum ten years' follow-up. *Int Orthop.* Mar 31 2015. PMID 25820838
16. Daniel J, Pradhan C, Ziaee H, et al. Results of Birmingham hip resurfacing at 12 to 15 years: a single-surgeon series. *Bone Joint J.* Oct 2014; 96-B(10):1298-1306. PMID 25274912
17. Murray DW, Grammatopoulos G, Pandit H, et al. The ten-year survival of the Birmingham hip resurfacing: an independent series. *J Bone Joint Surg Br.* Sep 2012; 94(9):1180-1186. PMID 22933488
18. Matharu GS, McBryde CW, Pynsent WB, et al. The outcome of the Birmingham Hip Resurfacing in patients aged < 50 years up to 14 years post-operatively. *Bone Joint J.* Sep 2013; 95-B(9):1172-1177. PMID 23997127
19. Pailhe R, Matharu GS, Sharma A, et al. Survival and functional outcome of the Birmingham Hip Resurfacing system in patients aged 65 and older at up to ten years of follow-up. *Int Orthop.* Jun 2014; 38(6):1139-1145. PMID 24370976

20. Amstutz HC, Le Duff MJ, Campbell PA, et al. Clinical and radiographic results of metal-on-metal hip resurfacing with a minimum ten-year follow-up. *J Bone Joint Surg Am.* Nov 2010; 92(16):2663-2671. PMID 21084576
21. Kim PR, Beaulé PE, Laflamme GY, et al. Causes of early failure in a multicenter clinical trial of hip resurfacing. *J Arthroplasty.* Sep 2008; 23(6 Suppl 1):44-49. PMID 18722302
22. Nunley RM, Zhu J, Brooks PJ, et al. The learning curve for adopting hip resurfacing among hip specialists. *Clin Orthop Relat Res.* Feb 2010; 468(2):382-391. PMID 19779950
23. Gross TP, Liu F, Webb LA. Clinical Outcome of the Metal-on-Metal Hybrid Corin Cormet 2000 Hip Resurfacing System: An up to 11-Year Follow-Up Study. *J Arthroplasty.* Apr 2012; 27(4):533-538 e531. PMID 21908168
24. McGrath MS, Marker DR, Seyler TM, et al. Surface replacement is comparable to primary total hip arthroplasty. *Clin Orthop Relat Res.* Jan 2009; 467(1):94-100. PMID 18797977
25. Ball ST, Le Duff MJ, Amstutz HC. Early results of conversion of a failed femoral component in hip resurfacing arthroplasty. *J Bone Joint Surg Am.* Apr 2007; 89(4):735-741. PMID 17403794
26. de Steiger RN, Miller LN, Prosser GH, et al. Poor outcome of revised resurfacing hip arthroplasty. *Acta Orthop.* Feb 2010; 81(1):72-76. PMID 20170416
27. Reito A, Puolakkka T, Elo P, et al. Outcome of Birmingham hip resurfacing at ten years: role of routine whole blood metal ion measurements in screening for pseudotumours. *Int Orthop.* Nov 2014; 38(11):2251-2257. PMID 25030963
28. Williams DH, Greidanus NV, Masri BA, et al. Prevalence of pseudotumor in asymptomatic patients after metal-on-metal hip arthroplasty. *J Bone Joint Surg Am.* Dec 7 2011; 93(23):2164-2171. PMID 22159851
29. Kwon YM, Ostlere SJ, McLardy-Smith P, et al. "Asymptomatic" pseudotumors after metal-on-metal hip resurfacing arthroplasty: prevalence and metal ion study. *J Arthroplasty.* Jun 2011; 26(4):511-518. PMID 20591612
30. Steffen RT, Pandit HP, Palan J, et al. The five-year results of the Birmingham Hip Resurfacing arthroplasty: an independent series. *J Bone Joint Surg Br.* Apr 2008; 90(4):436-441. PMID 18378915
31. Olliviere B, Darrah C, Barker T, et al. Early clinical failure of the Birmingham metal-on-metal hip resurfacing is associated with metallosis and soft-tissue necrosis. *J Bone Joint Surg Br.* Aug 2009; 91(8):1025-1030. PMID 19651828
32. Mont MA, Seyler TM, Ulrich SD, et al. Effect of changing indications and techniques on total hip resurfacing. *Clin Orthop Relat Res.* Dec 2007; 465:63-70. PMID 17891034
33. Greclula MJ. Resurfacing arthroplasty in osteonecrosis of the hip. *Orthop Clin North Am.* Apr 2005; 36(2):231-242, x. PMID 15833461
34. Stulberg BN, Fitts SM, Zadzilka JD, et al. Resurfacing arthroplasty for patients with osteonecrosis. *Bull NYU Hosp Jt Dis.* 2009; 67(2):138-141. PMID 19583542
35. Beaulé PE, Amstutz HC, Le Duff M, et al. Surface arthroplasty for osteonecrosis of the hip: hemiresurfacing versus metal-on-metal hybrid resurfacing. *J Arthroplasty.* Dec 2004; 19(8 Suppl 3):54-58. PMID 15578554
36. Lombardi AV, Jr., Barrack RL, Berend KR, et al. The Hip Society: algorithmic approach to diagnosis and management of metal-on-metal arthroplasty. *J Bone Joint Surg Br.* Nov 2012; 94(11 Suppl A):14-18. PMID 23118373
37. California Technology Assessment Forum. Metal on Metal Hip Resurfacing as an alternative to Total Hip Arthroplasty. 2011; <http://www.ctaf.org/assessments/metal-metal-hip-resurfacing-alternative-total-hip-arthroplasty-0>. Accessed July 7, 2015.
38. American Academy of Orthopaedic Surgeons (AAOS). Modern metal-on-metal hip resurfacing. 2009; <http://www.aaos.org/news/aaosnow/feb10/cover1.asp>. Accessed July 7, 2015.
39. National Institute for Health and Care Excellence (NICE). Technology Assessment 304, Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip 2014; <http://publications.nice.org.uk/total-hip-replacement-and-resurfacing-arthroplasty-for-end-stage-arthritis-of-the-hip-review-of-ta304/evidence-and-interpretation#clinical-effectiveness>. Accessed July 7, 2015.